Contains Nonbinding Recommendations

Draft Guidance on Glycopyrronium Tosylate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Glycopyrronium tosylate

Dosage Form; Route: Cloth; topical

Recommended Studies: Request for waiver of in vivo bioequivalence study requirements

A. To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of glycopyrronium tosylate cloth, EQ 2.4% Base should contain the same active drug ingredient in the same concentration and dosage form as the reference product and contain no difference in inactive ingredients or in other aspects of the formulation relative to the reference product that may significantly affect the local or systemic availability of glycopyrronium tosylate.

B. For a topical solution drug product that differs from the reference product in inactive ingredients [as permitted by the chemistry, manufacturing and controls regulations for Abbreviated New Drug Applications (ANDAs), 21 CFR 314.94(a)(9)(v)], the regulation specifies that the applicant must identify and characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

Additional Comments:

In general, evidence to demonstrate that the formulation of the test product should not alter the local and systemic availability of glycopyrronium tosylate, compared to that from the reference product may be based upon a comparison of the formulation composition as well as relevant quality and performance attributes of the test and reference products.

For example, the components and composition of the test and reference products may be demonstrated to be qualitatively (Q1) and quantitatively (Q2) the same, as defined in FDA's guidance for industry ANDA Submissions – Refuse-to-Receive Standards, the solution in the test and reference products may be shown to have a comparable pH, and the "cloth" material of the test and reference products may be shown to have an absorbency that is comparable. These and any other potentially relevant physical and chemical properties should be characterized for a minimum of three batches of the test and three batches (as available) of the reference product.

If the test product contains different inactive ingredients or other differences in the formulation compared to the reference product, additional quality and performance characterizations should be performed to mitigate the risk that any differences between the test and reference products

could affect the local or systemic availability of glycopyrronium tosylate, local irritation, or other aspects of the formulation interaction with the skin that may be relevant to the safety or efficacy of the drug product.

Note: A pharmaceutically equivalent drug product submitted in an Abbreviated New Drug Application (ANDA) should contain the same percentage of drug, the same volume of the formulation in the drug product and have the same dimensions (for the cloth) as the reference product.

Analytes to measure (in appropriate biological fluid): Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: Not applicable (other than as discussed above)

Dissolution test method and sampling times: Not applicable

Applicants intending to propose an alternative approach by which to demonstrate bioequivalence should refer to the guidance for industry *Controlled Correspondence Related to Generic Drug Development* and the guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* for additional information describing the procedures on how to clarify regulatory expectations regarding your individual drug development program.